

Full Text AR-96-001

## SKIN DISEASES RESEARCH CORE CENTERS

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## PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) in skin diseases. The Skin Diseases Research Centers (SDRCs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in skin diseases and to ensure greater productivity than from each of the separate projects.

## HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Skin Diseases Research Core Centers, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. An established clinical and research program in skin diseases should be present. At the time of award, the applicant institution cannot have another Skin Diseases Research Core Center funded by NIAMS. Foreign organizations are not eligible. Applications from racial/ethnic minority individuals and women and persons with disabilities are encouraged.

## MECHANISM OF SUPPORT

This RFA will use the NIH Core Center Grant (P30). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Investigators may request five years of support. The direct costs requested cannot exceed \$400,000 each year. The anticipated award date is March 1, 1997.

## FUNDS AVAILABLE

The direct costs requested may not exceed \$400,000 each year. The NIAMS intends to fund two SDRCs from this RFA in FY 1997, subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are \$1.2 million.

## RESEARCH OBJECTIVES

Research in skin diseases is at a stage where a number of areas are making broad advances that can be effectively fostered by research core centers. Examples of these areas include, but are not limited to:

- o stratum corneum: biochemistry, structure, function
- o epidermis: differentiation, keratinization, cellular constituents
- o dermal-epidermal junction: structure, functions, diseases
- o skin as an immunological organ
- o autoimmune skin diseases
- o dermis: structural components, diseases

The choice of research problem upon which the SDRC would focus is made by the principal and collaborating currently funded investigators.

The SDRCs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities.
2. Limited funds for pilot and feasibility studies.
3. Program enrichment activities.

An SDRC should be an identifiable organizational unit within a university-affiliated medical center. An Administrative Core should be proposed to coordinate the Center and administer the program enrichment activities. One or more research cores may be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics).

A pilot and feasibility study program provides modest research support for a limited time (3 years or less) to enable eligible investigators to explore the feasibility of a skin diseases-related concept and amass sufficient data to pursue it through other funding mechanisms. Eligible investigators include

1. an established investigator in skin diseases or related areas with a proposal for testing the feasibility of a new or innovative idea that is skin diseases-related but represents a clear and distinct departure from the investigator's ongoing research interest;
2. an established, supported investigator with no previous work in skin diseases or related areas who is willing to test the applicability of his/her expertise on a skin diseases-related problem; and

3. a new investigator who has not been a principal investigator in a past or current NIH research project grant (R01, R29, P01). New investigators should be clearly independent and have a faculty appointment higher than that of postdoctoral fellow or research associate.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SDRC staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

## SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one-day meeting in Bethesda, MD with NIAMS staff.

## INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and reprinted in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

## LETTER OF INTENT

Prospective applicants are asked to submit, by May 10, 1996, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the selection of reviewers. The letter of intent is to be sent to Dr. Julia B. Freeman at the address listed under INQUIRIES.

## APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 6701 Rockledge Drive, Room 3034, MSC 7762, Bethesda, MD 20892-7762, telephone 301/435-0714, email: girg@drupo.drg.nih.gov.

Special guidelines have been developed for the SDRC program in NIAMS. These guidelines should be used in assembling the application. See INQUIRIES for obtaining a copy of these guidelines.

The RFA label available in the PHS 398 (rev. 5/95) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, "Skin Diseases Research Core Center", and number, "AR-96-001" must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies of the application in one package to:

DIVISION OF RESEARCH GRANTS  
NATIONAL INSTITUTES OF HEALTH  
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710  
BETHESDA, MD 20892-7710  
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send two additional copies of the application to:

Review Branch

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building, Room 5AS.25U - MSC 6500

Bethesda, MD 20892-6500

Bethesda, MD 20814 (for express/courier service)

Applications must be received by June 19, 1996. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed.

This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

#### REVIEW CONSIDERATIONS

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

The factors to be considered in the evaluation of the merit of each application will be those used in the review of the cores in standard multi-project research grant applications. Applicants should clearly demonstrate the ways in which the SDRC will build the local research program, will support on-going projects and will attract both senior and new investigators to skin diseases research. Each application must be thorough and complete enough to stand on its own and should be prepared as if no site visit will occur. Additional materials or revisions will not be accepted after the receipt date. It is strongly recommended that, if appropriate, Institutional Review Board (IRB) and Institutional Animal Care and Use committee (IACUC) approval be secured before the application is submitted. Otherwise, it is the applicant's responsibility to ensure these certifications are sent to the NIAMS Review Branch within 60 days of the receipt date. Applications failing to comply with this requirement will be returned without review.

## Review Criteria

- o scientific, technical, or medical significance and originality of proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of the resources necessary to perform the research;
- o appropriateness of the proposed budget and duration in relation to the proposed research;
- o adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. The initial review group will also examine the provisions for the protection of human and animal subjects, the safety of the research environment, and conformance with the NIH Guidelines for the Inclusion of Women and Minorities as Subjects in Clinical Research.

Additional factors to be considered in evaluation of the scientific merit of each SDRC application will include an evaluation of the independently funded biomedical research base, the appropriateness of the proposed cores, the quality of the proposed pilot and feasibility studies, and their proposed management. The evaluation of the biomedical research base will encompass the record of research training and the institution's commitment to the Center program.

## Research

- o The overall purpose of a SDRC is to increase the quantity and quality of research in skin diseases within an applicant institution. The expected effect of the SDRC on the capacity of the institution to conduct skin diseases research and to secure extramural funding will be a factor in review.
- o A base of ongoing high quality research dependent on core resources and the potential to launch additional appropriate research activities is a prerequisite for the establishment or continuation of a SDRC and is an important component of the review.

- o The merit of the pilot and feasibility grant program proposed in the new application and the quality of pilots funded in the previous award period for competing continuations will be an important criterion for evaluating pilot programs.

#### Administration

- o The scientific and administrative leadership ability of the SDRC director and his/her staff, and their commitment and ability to devote adequate time to the management of the SDRC program.
- o The proposed administrative organization.
- o Coordination of ongoing research and its use of the SDRC. This includes various mechanisms of internal monitoring.

#### Cores

- o How does each proposed core fit into the overall research program?  
Will it enhance collaborative and/or interdisciplinary research?
- o Would the proposed core(s) duplicate existing resources or services? If so, are the requested new resources justified? Do other grant funds already provide any of the requested capabilities?

#### AWARD CRITERIA

The anticipated date of award is March 1, 1997. The primary factors determining the award will be the priority score and the availability of funds. Since the NIAMS is interested in funding only the best research, individual pilot and feasibility projects or cores of lesser quality will not be funded, even if recommended for approval, under the "umbrella" of the SDRC mechanism.

#### INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Inquiries regarding programmatic issues and letters of intent may be directed to:

Dr. Julia B. Freeman  
Centers Program, EP

National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Natcher Building, Room 5AS.19F - MSC 6500  
Bethesda, MD 20892-6500  
Telephone: (301) 594-5052  
FAX: (301) 480-4543  
Email: [freemanj@ep.niams.nih.gov](mailto:freemanj@ep.niams.nih.gov)

Copies of the guidelines for the SDRC program may be obtained from:

NIAMS Clearinghouse  
1 AMS Circle  
Bethesda, MD 20892-3675  
Telephone: (301) 495-4484  
FAX: (301) 587-4352

Direct inquiries regarding fiscal matters to:

Sally A. Nichols  
Grants Management Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Natcher Building Room 5AS.49F - MSC 6500  
Bethesda, MD 20892-6500  
Telephone: (301) 594-3535  
FAX: (301) 480-5450  
Email: [nicholss@ep.niams.nih.gov](mailto:nicholss@ep.niams.nih.gov)

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78<sup>th</sup> Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-

Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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[Return to RFAs Index](#)

[Return to NIH Guide Main Index](#)